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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ATTACHMENT TO ADVISORY ACTION

Applicants argue that examiners statement, "[It] is well known in the art that maltitol is a HSH (as evidenced by the Federal Register)," is inaccurate. Rather, applicants assert that the Federal Register, states that "syrups, hydrolyzed starch, hydrogenated [the Federal Register term for HSH] contain various amounts of maltitol, sorbitol and higher order polyols or polysaccharides". To further clarify examiner's position, attention is drawn to CalorieControl.org which states that "[t]he term hydrogenated starch hydrolysate can correctly be applied to any polyol produced by the hydrogenation of the saccharide products of starch hydrolysis, in practice, however, certain polyols such as sorbitol, mannitol and maltitol are referred to by their common chemical names" (p. 1/paragraph 3, lines 1-2). Clearly, maltitol meets this criterion.

Further, CalorieControl.org also states that "hydrogenated starch hydrolysate is more commonly used to describe the broad group of polyols that contain substantial quantities of hydrogenated oligo- and polysaccharides in addition to any monomeric or dimeric polyols (sorbitol/mannitol or maltitol, respectively). Common names for major HSH subgroups have, therefore, been developed. These common names are generally based on the most prevalent polyol comprising the HSH. For example, polyols containing . . . maltitol as the majority component are called maltitol syrups" (p.1/paragraph , lines 2-6; paragraph 4, lines 2-6). Therefore, while it is true that a HSH may contain ***various*** amounts of sorbitol, mannitol and maltitol, an HSH containing maltitol as the predominate polyol would be called a maltitol syrup. A skilled artisan would be likely to use a maltitol syrup, such as Cerestar Maltidex M, 16311, as

maltitol. Clearly, maltitol syrup (i.e. Cerestar Maltidex M 16311), an HSH, meets the criterion for a maltitol.

Applicants argue that that examiner fails to note the following teachings of Reed et al.: "preferably less than about 4% of the alditols will have a DP of 3 or greater. Most preferably the syrup will consist essentially of sorbitol, a plasticizing agent selected from glycerin, propylene glycol and mixtures thereof and an anticrystallization agent selected from maltitol, mannitol and mixtures thereof." Further, applicants argue that while Reed et al. would tolerate a small amount of a HSH material in the syrup, Reed et al. clearly teaches that the syrup is to contain an anticrystallization agent selected from alditols other than sorbitol and having a DP of 1 or 2 and thus it would not have been obvious from Reed et al. to use a material that was 22% alditols with a DP of 3 or greater and 76% maltitol as a substitute for the plain maltitol (or combined maltitol and mannitol) of Reed et al.. While examiner does note the teachings of Reed et al., the applicant's interpretation is flawed. Reed teaches that less than 4% of the alditols will have a DP of 3 or greater where the alditols comprise about 60% to about 92% sorbitol and about 8% to about 40% alditols other than sorbitol with a DP of 1 or 2 (C5/L20-30). Since Cerestar teaches a material with 76% maltitol and 22% alditols having a DP of 3 or greater, a syrup containing 85% sorbitol and 15% Cerestar Maltidex M 16311 would contain 11.4 % alditols other than sorbitol having a DP of 1 or 2 (i.e. maltitol) and 3.3% alditols having a DP of 3 or greater.

Applicants argue that examiners arguments regarding unexpected results are misdirected because they are not applicable to the primary unexpected results of the present invention - that a single syrup of the present invention can be used at commercially significant levels to make both acceptable stick gum products and coated gum products, while the syrup of Reed could not be so

used. Applicant's argument is unfounded. The examiner's arguments are directed to all alleged unexpected results including the primary unexpected result of this invention. The question as to whether unexpected advantage has been demonstrated is a factual question. *In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984). Thus, it is incumbent upon applicant to supply the factual basis to rebut the prima facie case of obviousness established by examiner. See, e.g., *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972). The applicants have failed to show that the syrup of the present invention can be used at commercially significant levels to make both acceptable stick gum products and coated gum products, while the syrup of modified Reed et al. can not be used.

First, the applicants' evidence of nonobviousness is deficient in that it does not show that the syrup defined by their independent claims to be unexpectedly superior to the sorbitol syrup compositions of modified Reed et al. The disclosure of Reed et al. is not limited solely to the information contained in Tables I-IV. Specifically, as noted above, the reference clearly suggests that alditols with a DP of 3 or greater may be present at a ratio to alditols with a DP of 1 or 2 of less than 2:3 (C3/L11-13). The examples in Tables I-IV only compare the syrup of the present invention to one made without alditols having a DP of 3 or greater. Thus, since the reference allows for syrups containing alditols with a DP of 3 or greater, a closer comparison would have been with syrups containing alditols with the ratio disclosed in Reed et al. (C3/L11-13).

Second, while paragraph 0089 of the specification states that the inventive sugarless syrup can be successfully used in a variety of pellet gum , there is no data to show that syrup of modified Reed et al. cannot. In fact, paragraph 0090 of the specification states that "sensory and

other tests showed the gum centers made with the inventive sugarless syrup were similar in texture to the corresponding comparative samples."

Third, it is unclear what the specific unexpected and surprising results are. The only discussion appears to be in paragraphs 87-89 which states that the overall cost of example 3 "may" be less than the comparative example C, that in example 4 it is "anticipated" that the shelf life would improve, and if a pellet gum would have been made with the comparative syrup it is "expected" it would have been too soft. These statements are conclusory without any evidence to support them. Unexpected results must be established by factual evidence; mere argument or conclusory statements in the specification do not suffice. *In re Geisler*, 116 F3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Circ. 1977) (quoting *In re De Blauwe*, 736 F2d 699, 705, 222 USPQ 191, 196 (Fed. Cir 1984)).

Applicants argue that there is nothing in Reed that states that the same syrup could be used to make both stick and coated pellet gum. However, the applicants concede that a gum composition made using a syrup taught by Reed can be formed into pellets. Examiner does not suggest that Reed et al. disclose a ***coated*** pellet gum, but instead uses Dogliotti to teach a coated gum. Dogliotti teaches coating gum (C1/L28-30, C2/L64-67) with a sugarless coating (see xylitol, Abstract). Dogliotti teaches that sugarless coating can help preserve the core and impart sweetness and desirable texture to the final product (C1/L19-32). Given that Reed et al. disclose a composition that can be formed into pellets, since Dogliotti teaches coating gum to help preserve the core and impart sweetness and desirable texture to the final product, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated to the pellet gum of modified Reed et al.

Applicants point to paragraph 9 of the present specification that discusses Reed as well as paragraphs 11 and 34-38 as evidence of unexpected results. However, while these portions of the specification discuss the advantages of the present invention, applicants have not provided proper evidence, i.e. data, to support this position.

Applicants compare the facts of the current invention to those of *Ex Parte Mead Johnson & Co.*, 227 U.S.P.Q. 78 (Board of Patent Appeals and Interferences, 1985) and argues that the surprising result provides a showing of nonobviousness. Applicants' argument is misdirected. The teachings of *Ex Parte Mead Johnson & Co.* are not applicable to the current invention. Absence of property which a claimed invention would have been expected to possess based on the teachings of the prior art is evidence of unobviousness. *Id.* In the instant case, applicant is

not showing that the presently claimed composition does not possess the property of being used in both stick and coated pellet gum.

Applicants argue that nothing in the secondary reference, Maltidex M 16311 (Cerestar), teaches that by adding HSH to the Reed syrup one would have been able to make a syrup that did work for coated pellet gum. The examiner does not suggest this result. However, note that while Cerestar does not disclose all the features of the present claimed invention, Cerestar is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, namely a maltitol syrup containing 76% maltitol and 22% hydrogenated oligosaccharides having a DP of 3 or greater for use in chewing gum applications as an anticrystallization agent, and in combination with the primary reference, discloses the presently claimed invention.

Applicants argue that the discovery that the prior art was incorrect in suggesting that a Reed syrup could be used to make a pellet gum, and finding a solution to the problem of a syrup that could be used for both stick gum and coated pellet gum, evidences a nonobvious innovation worthy of patent protection. Applicants' argument is not found persuasive. Statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a structural difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art apparatus (or process). See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the

preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Applicants argue that the claims require the syrup comprise over 30%, about 30% to 55% and approximately 25% to about 65% of the chewing gum formulation and that at such high levels the syrup of Reed does not make an acceptable pellet coated gum product. Applicants do not provide any evidence to show that at these levels the syrup of Reed et al., as modified by Cerestar, does not make an acceptable pellet coated gum product.

Further, applicants argue that the claims require for the syrup to include, on a dry basis about 8% to about 15% plasticizing agent while Reed specifies that its syrup, on a dry basis, has about 15% to about 56%, and preferably about 20% to about 40% plasticizing agent and that is believed that the high level of glycerin in the syrup of Reed contributes significantly to the inability of the Reed syrup to make acceptable coated pellet gum products. Applicants do not provide any evidence to show that the syrup of Reed et al., containing the high level of glycerin, could not be used to make an acceptable coated pellet gum product. Further, while the overlap between the claimed amount of plasticizer and that disclosed by Reed is only at one point, i.e. about 15%, the fact remains that there is overlap. Additionally, it is noted that with the exception of claims 11-13, of the remaining claims that require amount of plasticizer, these amounts include about 5% to about 20%, about 8% to about 20%, and about 8% to about 25% plasticizer. The amount of plasticizer disclosed by Reed clearly overlaps these amounts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874.

The examiner can normally be reached on Monday - Thursday;7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794